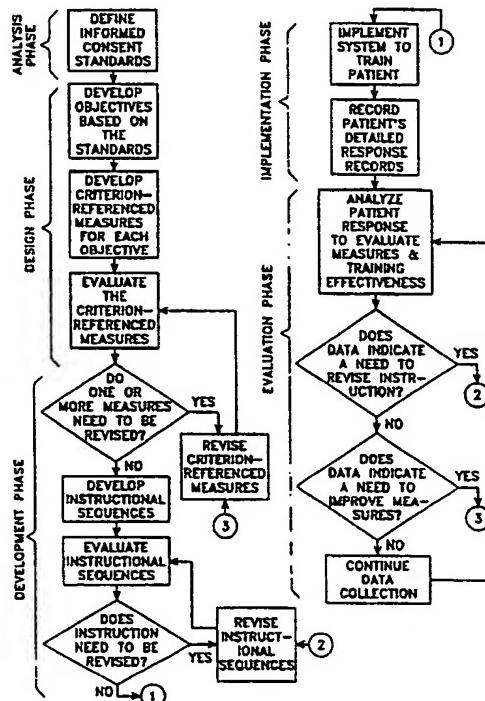




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<p>(54) Title: METHODS FOR ESTABLISHING CERTIFIABLE INFORMED CONSENT FOR A MEDICAL PROCEDURE</p> <p>(57) Abstract</p> <p>A method for establishing certifiable patient informed consent for a medical procedure, where, in one embodiment, the patient interacts with a video training system until mastery of all required information is successfully achieved. Training techniques which permit elicitation of measurable behaviors from a patient as a guide to discerning the level of knowledge of the patient are utilized. Certification is only granted when the measurable behavior approximately coincide with the legal and medical standards for establishing informed consent. The system is capable of adapting to various medical procedures, as well as various patient attitudes and knowledge bases, while still maintaining a level of consistency throughout. In one embodiment, a minimum probability of understanding may be preset, and the training procedure will continue until the actual statistical probability of understanding is at least equal to the preset minimum. An interactive nature of the system is present in the present system for facilitating the training process and continuously monitoring the patient's knowledge.</p> <pre> graph TD subgraph ANALYSIS_Phase [ANALYSIS PHASE] A[DEFINE INFORMED CONSENT STANDARDS] --> B[DEVELOP OBJECTIVES BASED ON THE STANDARDS] B --> C[DEVELOP CRITERION-REFERENCED MEASURES FOR EACH OBJECTIVE] C --> D[EVALUATE THE CRITERION-REFERENCED MEASURES] end subgraph DESIGN_Phase [DESIGN PHASE] E{DO ONE OR MORE MEASURES NEED TO BE REVISED?} E -- NO --> F[DEVELOP INSTRUCTIONAL SEQUENCES] F --> G[EVALUATE INSTRUCTIONAL SEQUENCES] G --> H{DOES INSTRUCTION NEED TO BE REVISED?} H -- NO --> I[CONTINUE DATA COLLECTION] H -- YES --> J[REVISE INSTRUCTIONAL SEQUENCES] J --> E end subgraph DEVELOPMENT_Phase [DEVELOPMENT PHASE] E -- YES --> K[REVISE CRITERION-REFERENCED MEASURES] K --> D end subgraph IMPLEMENTATION_Phase [IMPLEMENTATION PHASE] L[IMPLEMENT SYSTEM TO TRAIN PATIENT] M[RECORD PATIENT'S DETAILED RESPONSE RECORDS] N[ANALYZE PATIENT RESPONSE TO EVALUATE MEASURES & TRAINING EFFECTIVENESS] O{DOES DATA INDICATE A NEED TO REVISE INSTRUCTION?} P{DOES DATA INDICATE A NEED TO IMPROVE MEASURES?} Q[CONTINUE DATA COLLECTION] R[REVISE INSTRUCTIONAL SEQUENCES] S{DOES INSTRUCTION NEED TO BE REVISED?} T[REVISE INSTRUCTIONAL SEQUENCES] U{DOES INSTRUCTION NEED TO BE REVISED?} V[REVISE INSTRUCTIONAL SEQUENCES] W{DOES INSTRUCTION NEED TO BE REVISED?} X[REVISE INSTRUCTIONAL SEQUENCES] Y{DOES INSTRUCTION NEED TO BE REVISED?} Z[REVISE INSTRUCTIONAL SEQUENCES] AA{DOES INSTRUCTION NEED TO BE REVISED?} BB[REVISE INSTRUCTIONAL SEQUENCES] CC{DOES INSTRUCTION NEED TO BE REVISED?} DD[REVISE INSTRUCTIONAL SEQUENCES] EE{DOES INSTRUCTION NEED TO BE REVISED?} FF[REVISE INSTRUCTIONAL SEQUENCES] GG{DOES INSTRUCTION NEED TO BE REVISED?} HH[REVISE INSTRUCTIONAL SEQUENCES] II{DOES INSTRUCTION NEED TO BE REVISED?} JJ[REVISE INSTRUCTIONAL SEQUENCES] KK{DOES INSTRUCTION NEED TO BE REVISED?} LL[REVISE INSTRUCTIONAL SEQUENCES] MM{DOES INSTRUCTION NEED TO BE REVISED?} NN[REVISE INSTRUCTIONAL SEQUENCES] OO{DOES INSTRUCTION NEED TO BE REVISED?} PP[REVISE INSTRUCTIONAL SEQUENCES] QQ{DOES INSTRUCTION NEED TO BE REVISED?} RR[REVISE INSTRUCTIONAL SEQUENCES] TT{DOES INSTRUCTION NEED TO BE REVISED?} TT -- NO --> CC TT -- YES --> DD DD --> EE EE --> FF FF --> GG GG --> HH HH --> II II --> KK KK --> LL LL --> MM MM --> OO OO --> PP PP --> QQ QQ --> TT end </pre>			



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**Methods for Establishing Certifiable Informed
Consent for a Medical Procedure**

I. TECHNICAL FIELD

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The present invention relates to methods for establishing informed consent to a medical procedure, particularly for medical procedures such as a hysterectomy, a blood transfusion, AIDS/HIV treatment, psychiatric treatment, dental procedures, anesthesia, and the like. More specifically, the present invention relates to 10 interactive methods for establishing within a predetermined probability that a patient, or his/her guardian, has understood the disclosed information regarding the medical procedure.

II. BACKGROUND ART

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Virtually every medical procedure performed in the United States, including psychiatric treatment and dental procedures, requires that the patient consent to the procedure. This consent may either be expressed or implied. A competent adult patient can implicitly consent to a procedure by his/her situation or his/her 20 actions. Examples of this type of consent would include certain emergencies and typical physical examinations. Consent to such procedures is implied by the patient. While it is frequently deemed acceptable, it is not the type of consent preferred by the medical community and is to be avoided where possible.

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Expressed consent is preferred by the medical community. At present, expressed consent is usually oral or written. The inherent difficulty in proving details with respect to oral consent makes this type of expressed consent less preferable for most health care providers. Using existing techniques, many non-emergency type surgical procedures require the patient to read and sign an 30 "informed consent" form. Admittedly, this can be awkward; it is well established, however. For example, the "Operating Room Administration Manual—Checklists, Guidelines & Forms" includes a checklist of clauses which may be included in the typical written consent form. In addition, a list of medical procedures requiring full disclosure is included as Exhibit 30-3 to this reference. These procedures, among 35 many others, are deemed to require not merely consent, but informed consent.

The author of an article discussing surgical informed consent suggests to establish legally-sufficient informed consent, at least three elements are required: (1) sufficient information in understandable terms, (2) competence on the part of the patient to reason, and (3) absence of coercion. (This reference, disclosed 5 below, contains much authoritative material on the subject of informed consent.)

These legal requirements can be burdensome to the medical practitioner. Not only does complying with such requirements take time, but the constantly changing state of the law makes merely remaining current in this developing field 10 a challenge. When properly fulfilled, it is even possible that the health care provider could spend more time obtaining consent to avoid lawsuits than practicing medicine. The present invention is designed to alleviate this imposition on medical personnel by providing a method of establishing certifiable informed consent. The disclosed system and methods improve the ability of achieving an "informed" state, 15 the credibility of having received "consent", and enhance the ability to prove in a court of law that informed consent was indeed established, should it be necessary.

For many years the only device used to indicate possible informed consent was a standard form, as mentioned previously. In some instances the form served 20 as a reference guide for the practitioner as he/she read from it to the patient. In other instances the form might have been handed to the patient along with a multitude of other forms, each requiring the patient's signature. It is very likely that, in haste, many of these informed consent forms are signed without ever having been read; even more likely is the fact that such forms are rarely truly 25 understood by the patient. One study has shown that on the average patients read 4.6 grade levels below their reported highest grade completed. The mean reading level in some communities was reported as low as third grade, with consent forms requiring a postcollege reading level (*Southern Medical Journal*, October 1991, vol. 84, p. 1172). This combined with the possible recklessness on the part of the 30 patient, as well as the medical provider, fueled by the litigious nature of our society, has contributed to the skyrocketing malpractice insurance fees experienced by many health care providers. These are, naturally, passed on to the patient in the way of higher medical fees charges. Most acutely however, the signed

informed consent form technique has failed in its primary purpose. Often it has not been deemed to sufficiently establish true "informed consent" by the patient.

To overcome this potential impact, written forms are often accompanied by 5 a verbal explanation or interview by the health care provider. This solution is undesirable for at least two reasons. First, it reintroduces the oral element in obtaining a consent. Second, unfortunately, informed consent interview techniques are not an area focused upon by most medical schools. Instead, new practitioners are usually expected to observe, assimilate, and personalize what 10 other colleagues do. While to a patient this interview may be no less important than the procedure itself, the health care provider may view it as a bothersome task that has little relevance to the procedure to be performed.

Even the standard informed consent forms currently used have often fatal 15 practical limitations. They can be inconsistently applied. Typically the forms are modified for each specific medical, dental or psychiatric procedure. While this is efficient, it rarely takes into account the impacts of the differing information to be conveyed, the differing manners in which it must be delivered (if read), and the differing attitudes of the patient. Each of these naturally affect the dependability 20 of the form. In addition, as each doctor tries to alter a general form for a specific procedure, personal biases can detract from the real goal of the process. Even if each of these limitations were recognized, until the present invention, it simply would not have been practical to tailor a document not only doctor to doctor, but also from day to day, and from patient mood to patient mood. This latter 25 aspect—that a given patient might have different needs from day to day or hour to hour—has been an aspect that, until the present invention, those skilled in the art could not readily address. Those skilled in the art, the doctors and lawyers, simply believed it was not possible to accommodate the needs of the patient to this degree. While the need for controlled consistency in this area has been openly 30 sought by consumer protection groups, medical groups, and malpractice insurance carriers, until the present invention it was not deemed practical to attempt to utilize a technique which could be varied to suit each specific occasion.

In order to meet these needs, the present invention utilizes techniques not traditionally applied to the informed consent field. Among these techniques is the use of video technology. The use of video as a training tool has been known and widely accepted in a number of fields. U.S. Patent Nos. 4360345 and 4907973, 5 both to Hon, disclose the use of computer/video systems for teaching health and medical education. U.S. Patent No. 4459114 to Barwick discloses the use of video to teach communication skills, while U.S. Patent No. 4948371 to Hall has applications in law enforcement training and military training. As the present invention recognizes, the video system's ability to provide consistency through 10 controlled presentation can be beneficially applied to the informed consent field as well. Video tape (VHS or beta) and video disk systems have been used in some hospitals, clinics and doctor offices, functioning to educate patients on a limited number of medical procedures. None, however are used to address the very important aspect of certifying or proving the patient had, without question, given 15 his or her informed consent. Given this known use of such a system, it might initially be considered surprising that the application of such a technology to the informed consent field was not recognized. This, however, may be a result of the diverse perspectives of the techniques traditionally involved.

20 The technology of using video as a training aid has been distinct from that of establishing informed consent. This is due to the goals involved, and may be highlighted by the goals of "teaching" and "training." The Oxford English Dictionary defines training as "bringing a person to a desired state or standard of efficiency by instruction and practice." Teaching on the other hand, is merely a 25 process of conveying information. While most patients would sit through a short film on the risks and alternatives as related to a hysterectomy, few would view such a video with the intent of being trained. Merely presenting a video would not significantly overcome the limitations of the prior art. For example, while the entire procedure may be explained in detail, the patient is capable of "tuning out" certain 30 information — just as he/she might ignore or overlook the statements of a doctor. In this case the medical practitioner may believe he/she has satisfied his/her responsibilities when in fact the patient is not truly consenting in an informed manner. The present invention overcomes this limitation by devising a

method for certifying not only the level of information conveyed to a patient, but the patient's level of understanding as well. The patient simply cannot be certified by the present invention and still have failed to understand the necessary aspects of the procedure.

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Another problem with both the informed consent form, and standard education video is the extent of the information. Too little, or too much information can be detrimental to the process of establishing informed consent. While most systems and forms might hope to err on the side of too much information, this "overkill" may cause a patient to fail to fully comprehend important elements. Naturally, too little information would also fall short on the informed side of the issue. According to a December 1987 article from *The American Journal of Surgery*, entitled "Surgical Informed Consent: What It Is and Is Not", by W. Sterling Edwards, M.D., et al., the courts have utilized two concepts as guidelines for the degree of information that must be provided to a patient—the professional standard and the lay standard.

The professional standard has been suggested to require that the medical practitioner disclose what is standard for the community. As the more objective rule, it is used by the majority of jurisdictions. The lay standard, known also as the material risk standard, has been suggested to require the practitioner to disclose what any reasonable person would want to know about the procedure. With respect to what type of information must be disclosed, the two standards are in agreement that the information need not be encyclopedic, and that any possible serious conditions, no matter how remote, should be disclosed. With both the standard informed consent form and the continuous video type patient education system, a patient is virtually locked into the presentation process. If it is too much information, the patient must usually endure. If the information conveyed is deficient, it falls to the patient to glean additional information from another source, such as a doctor or nurse. The present invention avoids placing this burden on the patient. Instead, through interaction with the patient, the information provided can be personalized to the patient's knowledge base regardless of which standard is utilized.

Documentation of consent is usually not required by law. Obviously, though, if a suit is filed against a practitioner, the more documentation available, the better. In many instances, both the patient's and the doctor's recall of the information presented can be poor and unreliable. Thus, a signed document may

5 be the only evidence to reliably evidence consent. The question still remains as to whether such consent was "informed", however. Did the practitioner read over all elements of the form? Did the patient? If either party read the form, did the patient understand the various terms used? Naturally, in a mere video presentation, similar concerns would arise. Prior to the present invention,

10 reproducing the events that transpired up to the point of signature was very difficult if not impossible. The present invention overcomes this limitation to protecting both parties before consent can be established.

The present invention, in its various methods, recognizes and addresses

15 these and other problems and overcomes many limitations encountered by those skilled in the art by bringing together, and bridging the gaps that have existed between the legal, medical, consumer and training fields with respect to establishing certifiable informed consent. Many devices and procedures have taught education of patients in the area of medical procedures. However, these

20 devices and procedures have typically considered only the consumer (patient) groups and the medical field. Other approaches have taken the perspective of the legal field in attempts to protect medical practitioners and their insurance carriers. Until the present invention, no one had taken the approach of training and certifying patients' knowledge in a pending medical procedure, despite the long felt

25 need for such certification, and the existence of the necessary implementing arts. Certainly problems such as proving "informed consent" exist in the field of informed consent (it might not be such a heavily litigated field otherwise), but such problems have gone unnoticed by those skilled in the art. Basically attempts at establishing patient informed consent were inadequate because those skilled in the

30 art failed to address and balance the needs of the patient, the doctor, the court system, and the insurer. The recognition by the present inventors that the problems encountered in the informed consent field could be solved by applying and modifying techniques of a training nature, and not an educational nature, lead

to the present invention. While other aspects of these training techniques have been known for some time, and while they have been used in various other fields, those skilled in the art of establishing informed consent have failed to recognize their value as solutions in the informed consent field. The prior art has taught 5 away from the present invention by stressing education of patients rather than training. Other areas of teaching away by the prior art are rooted in the desire for a single general form, rather than a process which adapts to the continuously varying characteristics of procedures, doctors, patients, and courts. Rather than supplying a system which affords only an incremental increase in performance and 10 design over the prior art, the present invention utilizes techniques which were not previously considered to achieve leaps in performance compared to the prior art.

III. DISCLOSURE OF INVENTION

15 The present invention discloses methods for establishing patient informed consent in conjunction with most medical procedures, such as used in hospitals, clinics, and doctors' offices. The disclosed methods provide a reliable and effective means for certifying each patient's level of understanding with respect to information furnished on a pending medical procedure. This invention serves to 20 establish a patient's consent to a medical procedure by applying training techniques, to facilitate learning, and to monitor the state of knowledge by providing an interactive system.

In general terms, the invention involves various embodiments of a training 25 technique for certifying informed consent. Many of the steps of this procedure achieve several different objects which, when combined, act to achieve the mentioned leaps in performance. In one instance, the invention takes into account legal and medical requirements for establishing informed consent while providing an interactive training process to allow optimal comprehension by the patient. The 30 invention may also involve periodic testing which permits the patient's knowledge to be confirmed and correlated against predetermined minimums for understanding. Still other features of the present invention include closed-loop testing, which

allows for the realization of the predetermined minimums, and various training media.

Accordingly, the present invention provides a method which establishes 5 certifiable patient informed consent. It acts to provide both medical practitioners and patients with a competent training system. The system may include an interactive video disk which may interact with the patient through question and response techniques which help to elicit measurable behaviors from the patient. In addition, accepted medical and legal standards can be used to establish 10 parameters in the system.

It is therefore broadly an object of the present invention to establish certifiable patient informed consent for a medical, dental or psychiatric procedure. A system may be designed which utilizes scientific training methods as a basis for 15 interacting with the patient. By using these training methods, the patient's level of knowledge in the various areas of the procedure may be monitored. Consequently, each patient can be certified as having understood, within a predetermined probability, and consented appropriately to the medical procedure. In addition, medical and legal standards for establishing informed consent are 20 typical reference parameters considered as the system is designed.

It is another object of the present invention to design a system which is capable of training a patient on various aspects of a medical procedure in an attempt to certify a patient's informed consent. A closed-loop system is used so 25 that any patient not achieving the desired level of understanding continues to be trained until such a level is achieved. It is therefore an object of the present invention to periodically test the patient's knowledge of the conveyed information. The purpose of this periodic testing is to force the patient to prove their understanding of the information.

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It is still another object of the present invention to elicit from the patient various measurable behaviors which may be correlated to the medical and legal standards utilized for establishing informed consent. This may be achieved by the

periodic testing, mentioned previously, which may incorporate any type of question and response format, such as, but not limited to, multiple choice, true/false or essay. Likewise, the interactive nature of the system may be accomplished by numerous types of training media.

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It is yet another object of the present invention to provide a system which is capable of certifying or proving the patient's level of knowledge. The present invention achieves this by capturing the patient's responses, and storing these responses. By doing so, any questions as to what the patient understood can be 10 easily recalled and related as a probability. In this fashion the invention meets a goal of correlating probabilities to establish a more defensible informed consent.

Naturally, further objects of the invention are disclosed throughout other areas of the specification and claims.

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IV. BRIEF DESCRIPTION OF DRAWINGS

The following descriptions and referenced drawings are for selected preferred embodiments of the present invention. Naturally, changes may be made 20 to the disclosed embodiments while still falling within the scope and spirit of the present invention and the patent granted to its inventors.

Figure 1 is a flow chart diagram showing one possible embodiment of the instructional system development (ISD) process.

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Figure 2 is a flow chart diagram of another possible embodiment of the ISD process.

Figure 3 is a flow chart diagram of one possible simplified interaction process 30 of the present invention.

Figure 4 is a flow chart diagram of one complex interaction process of the present invention.

Figure 5 is a blown-up flow chart diagram of the "presentation of objective n" as shown in box A of figure 4.

V. BEST MODE(S) FOR CARRYING OUT THE INVENTION

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As can be seen from the drawings, the basic concepts of the present invention may be embodied in many different ways. Figures 1 through 5 show flow diagrams which illustrate different approaches of the present invention, in both design and interaction process, to certify informed patient consent to a medical procedure. The process is designed to result in a condition that is sufficient to "certify" that the patient was adequately informed when signing a consent form. To "certify" it is intended that a point should be reached by the patient such that he/she has achieved at least a predetermined minimum criterion that the information was understood. Naturally, the minimum would be set at a level consistent with the goals of the present invention. Medical procedures are understood to include dental procedures and psychiatric treatments among others which may require disclosure to the patient before beginning. While particular embodiments of the invention will be described, it will be obvious that changes and modifications may be made without departing from the broad aspects of the present invention.

Before beginning the process of certification, requirements and standards must first be established. The system of the present invention uses a variation of a known training design and development technique called instructional system development (ISD). ISD is a systematic approach to the design, development, and continued refinement of instruction. The ISD model is explained in detail in a number of published references, including Instructional System Development, printed on July 15, 1986, by the United States Department of The Air Force; Systems Engineering Applied To Training by Silvern, published in 1972; The Systematic Design Of Instruction by Dick, et al, published in 1978; and, Instructional Product Development by Baker, et al, published in 1971. These articles are hereby incorporated by reference into the discussion of this application.

One embodiment of the ISD process used in the present invention may be summarized as follows:

- 5 (1) Establish, through analysis, the body of information that a patient might need to know about a particular medical procedure in order for them to legally and ethically be considered to be "informed";
- 10 (2) Establish a set of observable, measurable "objectives" which, if these objectives are achieved or "mastered", indicate that the patient comprehends this information and can apply it to his/her own situation;
- 15 (3) Develop, for each objective defined in step 2, a set of interactive behavioral measures (e.g., questions and patient answers to these questions) that evaluate whether or not the patient has met the objective;
- 20 (4) Evaluate the measures developed in step 3 with respect to their ability to discriminate persons who are knowledgeable about the procedure from those who are not;
- 25 (5) Develop a sequence of interactive, individualized instructions designed to facilitate patients' mastering the objectives established in step 2 (i.e., train them to provide the correct responses to the measures developed in step 3);
- 30 (6) Evaluate the effectiveness of the instruction and revise the instruction to correct any deficiencies;
- 35 (7) Implement the interactive sequences developed in steps 2 through 6 with actual patients. During the interaction with each patient, estimate the probability that the patient has mastered each objective. If the probability that the patient has mastered an objective does not meet or exceed a predetermined criterion, present additional instruction pertaining to that objective and repeat the evaluation;
- 40 (8) Collect detailed data on actual patients' responses in interacting with both the instruction and the measures. Use this data to refine both the measures and the instruction.
- 45

ISD, as shown in figures 1 and 2, begins with the "analysis phase." The development of the present embodiment may be commenced through careful evaluation of both legal and medical requirements for establishing informed consent. Such legal requirements may include, among others, those that are 5 statutorily dictated by state or federal governmental bodies, those that have been developed by case law in various jurisdictions, and those that have been sanctioned by the American Medical Association (AMA) or some other medical field governing body. The analysis includes evaluating all types of information relevant to a medical procedure and then selecting those items of information which are 10 considered necessary for establishing informed consent. Since these requirements may be broadly phrased and ambiguous in meaning, more definite parameters may be derived from these requirements. The present invention translates requirements into specific statements or standards deemed to be representative of the requirements. These may be statements concerning patients' knowledge about 15 specific medical procedures, knowledge of the benefits and risks of these procedures, and the patients' ability to apply this knowledge to their own situation. For instance, a court decision may result in new or altered requirements. These new or altered requirements would be translated into one or more specific standards. As these standards are translated—based on precedent and accepted 20 medical protocol—measurable patient behaviors, or objectives, may be defined.

This begins the next step of ISD, called the "design phase." In this phase, objectives are developed based upon the applicable standards. Each objective specifies the observable behavior(s) that would be expected from an informed 25 patient in response to a specific situation. For example, an objective might state that an informed patient would, when presented with a list of surgical risks, correctly recognize those risks associated with the surgical procedure under consideration. These objectives, in the present embodiment, are designed to correlate with or approximate as closely as possible the standards defined during 30 the analysis phase. The validity of this translation or correlation can be evaluated frequently, and the objectives may be altered or refined to better approximate the estimated standard.

A second aspect in the "design phase" is to develop, for each objective, a set of interactive behavioral measures (e.g., questions and patient answers to these questions) that evaluate whether or not the patient has met the objective. These interactions are designed as criterion-referenced measures. Criterion-referenced measures are designed to yield measurements that are directly interpretable in terms of specified performance standards (i.e. Is the respondent capable of performing the task represented by the corresponding objective? Does the respondent possess the knowledge required by the corresponding objective?). They are to be contrasted with the more commonly used norm-referenced measures (i.e., typical aptitude and achievement tests). The latter are designed to compare respondents with each other to rank them with respect to a particular set of skills or knowledge. Criterion-Referenced Measurement by James W. Popham, published in 1971, provides detailed discussion on this type of measurement. To supplement the background of this application the Popham reference is hereby incorporated by reference.

In the instances and applications of the present invention where the defined behaviors are elicited responses to stimuli, such as questions or statements, a statistical probability can be calculated to determine whether the objective has been achieved. The calculation may be as simple as a percentage of correct answers, or may, of course, be a more complex statistical calculation which may take into account aspects such as standard variance, normalization, random chance, error analysis, etc. In other instances the predetermined minimum criteria may be achieved to the satisfaction of a training expert, or the like. In addition to the ISD model training techniques, the present invention may also make use of artificial intelligence techniques for training and evaluation. Each of these techniques is known and implementable by any person with reasonable skill in the field of training.

A third aspect in the "design phase" can be to evaluate the criterion-referenced items to measure their ability to discriminate persons who have met the objective from those who have not met the objective. This may be accomplished through tryouts with two groups of persons: one group that can be assumed to be

fully informed regarding the medical procedure (e.g., medical interns, practicing physicians) and one group that can be assumed to be uninformed about the procedure (e.g. high school students). The tryout results for each item could be evaluated as shown in Table I and described below.

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In this hypothetical example, the item being validated has been administered to 30 members of each group. Ideally, all members of the Group A (the "Informed Group") would answer the item correctly and all members of the Group B (the "Uninformed Group") would answer it incorrectly. In practice, however, an 10 uninformed person may answer correctly because of an inadvertent clue in the item or a lucky guess. An informed person may answer incorrectly due to a poorly phrased question or through carelessness.

Table I

Responses	Informed Group	Uninformed Group	Totals
Correct	$p = \frac{27}{30} = .90$	$p = \frac{5}{30} = .17$	32
Incorrect	$p = \frac{3}{30} = .10$	$p = \frac{25}{30} = .83$	28
Totals	30	30	

(Example of Validation Data For A Measurement Item)

- 15 If there is a sufficient difference between the response patterns of the Informed and Uninformed Groups (as there is in this case), the item is considered to discriminate between groups and is retained. Otherwise, the item is dropped or revised and re-evaluated.
- 20 Naturally establishing even a 100% probability of patient understanding of the information provided is not helpful if the information provided is not all that is required for the particular medical procedure. The next step therefore, which

begins the ISD "development phase", is to develop a sequence of interactive, individualized instruction that is designed to facilitate patients' mastering the previously defined objectives and to evaluate their mastery through the previously developed and calibrated criterion-referenced measures. The instructional sequence 5 should be complete and directed explicitly at the objectives, accurate, brief, highly interactive, and capable of adapting to individual patients' requirements, needs, and interests.

While such a system may seem very simple to develop at first, to institute 10 it can require much preparation. This is no more apparent than in the next step which requires the designing of a system which will interact with the patient in a controllable fashion in an attempt to elicit the aforementioned measurable behaviors from the patient. Merely asking the patient, "Do you understand?" to elicit a "Yes" response is no more effective than the standard informed consent 15 form. Instead, the interaction is designed to force the patient to elicit more affirmative behaviors to prove an understanding of the selected information. It is believed that to do this effectively the training techniques as taught by the incorporated references are desirable. The reasoning for this belief is that while the essential correlation of patient behaviors to legal and medical standards may be 20 readily established, this is not the case for the structuring of queries, questions, or basic stimuli based upon the selected information. The questions must be capable of invoking the desired behavior from the patient. Furthermore, the presentation of the information should be complete, accurate and yet brief so as not to exceed the patient's attention span. Since this is a totally new application for these 25 techniques, these sources are hereby incorporated into the present application by reference.

Once legal and medical standards are estimated, behaviors defined, information selected, and appropriate stimuli developed the system must then be 30 constructed. The preferred embodiment of this invention might make use of various forms of computer-assisted instruction (CAI). This medium provides constant, tireless interaction with the patient, supports a wide variety of visual and auditory displays, is capable of varying the instructional sequence in response to

the patient's actions, and faithfully records each of the patient's overt responses. In this case, the system would be designed to use standard computer hardware technology, standard and special purpose computer software, and video disc or digitized audio and/or video, all of which is known and understood by those skilled
5 in training psychology and the computer arts.

The CAI medium may employ text, graphics, still and motion video, and audio in its presentations. The patient may interact with the medium by typing on a standard keyboard, pressing keys on a simplified key pad, touching parts of the
10 visual display (recognized by means of a touch-sensitive screen), indicating parts of the visual display via a mouse, track ball, or light pen, or by answering questions verbally (recognized by voice recognition techniques). The patient may be able to select the language (e.g., English, Spanish) and the vocabulary level used in the presentation.

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The CAI instructional sequence may adapt to the patient's requirements in either or both of two ways. First, the CAI instructional sequence will provide frequent opportunities for the patient to respond to content-related questions. These questions may be the criterion-referenced measures described above or they
20 may be lower-level, more specific questions that pertain to components of a single objective. If the patient responds correctly, the program will present new material. If the patient responds incorrectly, the program will review the previously presented material. This review may simply repeat the material or it may present it in a different form. Second, the patient may be asked to indicate how the
25 material is to be presented (e.g., language, vocabulary level, sequence of presentation, depth of presentation, and if and when to return to a previous part of the presentation in order to review it).

The criterion-referenced measures of whether the patient has achieved the
30 objectives may be embedded in the instructional sequence, may follow the presentation of material of each objective, or may be grouped at the end of the instruction. Alternative forms of the measures may also be presented at the beginning of the presentation. In this case, the patient's responses to the pre-

instruction measures would be used to determine which parts of the instructional sequence should be presented. This information may be presented to the patient as advice as to which topics to select for instruction or the program may simply route the patient to these topics.

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Other learning media may be used of course, such as continuous video or audio tape, records, books, and the like, but they can lack the ability to interact with the patient and to adapt the instructional sequence to the patient's needs. In some instances, however, this could certainly be an acceptable approach for certifying informed consent.

In a fourth ISD phase, the system is implemented in the field (e.g., physicians' offices, clinics, hospitals) and put into use with actual patients. Each patient who interacts with the system receives an instructional sequence tailored 15 to that patient's needs and interests. The anticipated system may be designed to "individualize" the process for each patient. Foreign languages, allegorical presentations, various reading and educational levels, and the like may be programmed into the system in order to allow a range of individuals to be trained by the same system.

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During the interaction with each patient, the system will estimate the probability that the patient has mastered each objective. If the estimated probability that the patient has mastered a particular objective does not exceed a predetermined value, the system will present additional instruction pertaining to 25 that objective and repeat the evaluation.

The close-looped training technique may make use of what is known by training psychologists as criterion referenced testing. Through the use criterion referenced testing, acceptable levels of understanding would be established and 30 the patient would be trained to meet or exceed these levels. This training and evaluation process is explained in the paper entitled "An Approach To The Evaluation Of Tailored Testing", presented by Kathleen M. Daubek and Dr. Wilson A. Judd (a co-inventor of the present invention) at the December 1973 annual

meeting of the Texas Psychological Association in Dallas, Texas. This paper is hereby incorporated by reference into the present application. In contrast to criterion referenced testing, most education methods utilize a ranking where students are referenced against one another. This is called norm referenced 5 testing. In such a system a score of less than 50% could become an acceptable (passing) level. In the field of informed consent a less than 50% understanding of the risks involved with a certain medical procedure would not be very defensible as having achieved an "informed" state. To accomplish the goal of achieving an informed state, measuring against a predetermined standard—as in criterion 10 referenced testing—is preferred. This allows the standard level to be controlled independent of individual scores. Naturally, the higher the level, the more repeating is likely to be required, but the more defensible the certification of informed consent. This level would be based on the estimated legal and medical standards which apply.

15

After the selected information is conveyed to the patient and he/she exhibits behaviors appropriate to approximately satisfy the legal and medical requirements for establishing informed consent, the patient is then certified. Certification may take a variety of forms, the most logical perhaps being a printed summary of the 20 selected information, questions, and/or responses, or any part thereof, with standard clauses and a signature line for the patient.

In addition, it is anticipated that the entire interaction between the patient and the system could be captured and stored indefinitely. The value of this aspect 25 would be in later deliberations which may be expedited if substantial proof could be provided as to the patient's understanding of the medical procedure at the time of issuing his/her informed consent. At such a time some form of statistical analysis may be provided as to the probability of the patient's understanding of the various aspects of the medical procedure (ie., prove achievement of objectives).

30

While development of the system is one aspect of the present invention, its practical application and use is also key for establishing certifiable informed consent. As shown in figures 3, 4 and 5 the preferred embodiments begin with

the training of the patient as to the various aspects of the required medical procedure. Figure 3 illustrates a simple interactive training procedure, while figure 4 is illustrative of a more complex embodiment. Figure 5, a detailed flow chart of box A of figure 4, expands on the complex training procedure, and particularly the 5 presentation of each objective. The training technique is broken down into three steps. First, the patient watches and listens to a brief presentation on the medical procedure. The presentation may single out one aspect of the procedure, such as the risks, or it may touch on all the areas of concern. After this brief presentation the patient's comprehension of this information is evaluated in the second step, as 10 discussed earlier. In this step, a set of queries, questions or stimuli may be presented, and time then allowed for the patient to respond. It is anticipated that the queries could be presented as a set of considerations related to the medical procedure, and whereby the patient could then react to the considerations by eliciting a behavioral response—such as touching the video screen, speaking 15 aloud, or the like. The responses, which are measurable behaviors, are measured to approximately coincide with the estimated legal and medical standards to determine the sufficiency of the response. In some cases, responses may be either right or wrong, and in other cases they may be incomplete—that is, for example, if a patient is asked to describe three risks of undergoing the medical procedure as 20 disclosed by the CAI, he/she may only be able to remember two. Wrong and incomplete responses may be adequate to determine an insufficient correlation to the estimated standards. Statistically speaking, as the number of events (patients using the interactive system) increases the measuring of the behaviors may be adjusted to achieve better coincidence between the aspects established through 25 the behavioral responses and those required by legal and medical standards.

The third step involves determining whether the patient's responses sufficiently approximate the legal and medical standards for establishing informed consent—that is, did he/she understand. This may be accomplished, as 30 mentioned previously, by calculating an actual statistical probability that an understanding was achieved by the patient. This probability may then be compared to the predetermined minimum acceptable probability, as explained earlier. If the actual probability is greater than the acceptable this would indicate

an acceptable condition, and a second training session may be started. If, however, the actual probability is less than the latter, this might indicate a suboptimal understanding, and require re-training in this objective. Re-training would continue with periodic evaluation until at least the minimum probability of 5 understanding is achieved. This closed-loop training technique will continue until mastery of all aspects presented is achieved by the patient.

- The interactive nature of the present invention facilitates learning by the patient, and allows continuous monitoring of patients' levels of knowledge.
- 10 Furthermore, the dissemination of information through CAI is more conducive to a consistent presentation on a day-to-day, and even patient-to-patient basis. Even though each patient will differ in attitude, intelligence, and other personality traits, the system will adapt its instruction to assure that almost all if not all patients achieve at least the minimum level of knowledge established by the objectives.
- 15 This relieves the doctor of subjectively trying to determine if a patient truly understands what has been explained. This training approach serves to remove variance from the informed consent procedure due to individual human character. The establishment of the informed consent will be affected by neither a patient's submissive nature, nor a patient's confused state of mind, nor a doctor's busy
- 20 schedule. Rather, the instructional sequence will present a consistent body of information in a way that accommodates to each patient's needs.

Each of the patient's interactions with the system, each overt response, and the stimulus to which this response was made will be recorded and stored. This 25 data will then be available for two purposes. First, the complete record of an individual patient's interactions, including their final correct responses to the criterion-referenced measures, will be available if a question concerning informed consent should arise at a later date. Second, as part of the fifth or "evaluation phase" of the ISD process, data from multiple patients will be used to analyze and 30 refine and improve both the criterion-referenced measures and the instructional sequences.

To better understand the present invention an example of the process of one embodiment is discussed. Naturally this is a fictitious example, and should not serve to limit the scope of coverage afforded the patent(s) granted on this invention.

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Example

Scenario: Patient A is about to be admitted to the hospital under the care of Dr. Smith to undergo an abdominal (total) hysterectomy. Before the day of the scheduled surgery Dr. Smith will instruct Patient A to view the disclosure requirements of the procedure on a CAI system (the "invention"). Patient A will agree to view the CAI disclosure.

Procedure: Patient A will be situated, perhaps in a private room or waiting area, to begin review of the CAI. Section I/Part 1: Patient A will be presented background information on abdominal hysterectomies, such as some general information on the medical procedure, and perhaps why it was probably recommended for her condition. At any time during presentation, it may be possible for Patient A to input a command (such as touch the screen, or press a button) to advance to, or return to a specific section/part. Section I/Part 2: Patient A will now be presented with a variety of open-ended questions, such as:

- List 2 conditions which may require an abdominal hysterectomy?
- What is the average time for an abdominal hysterectomy surgery?
- Which of the following types of anesthesia will you require?

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Section I/Part 3: Patient A will then be encouraged to respond to each query, and each response evaluated by the system. Patient A answers all three questions correctly. Since no incorrect responses were made, the system estimates that Patient A has mastered this objective and Patient A will then be advanced to the next section.

Section II/Part 1: Patient A will now be presented with the risks inherent to an abdominal hysterectomy, including undergoing a general anesthesia. Patient A decides she is well aware of all the risks and advances the CAI to the next part of the section. Section II/Part 2: Patient A will now be presented with a variety of open-ended questions, such as:

- What are the 4 most common complications of an abdominal hysterectomy?
- What are 3 critical complications of an abdominal hysterectomy?
- Which of the following post-operative discomforts is not typical for an abdominal hysterectomy?
- How long is the standard recovery period for an abdominal hysterectomy?
- List 3 minor complications which may be experienced after surgery?

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Section II/Part 3: Patient A will again be encouraged to respond to each query, and each response evaluated by the system. Of the five questions, Patient A answers four correctly. The question pertaining to common complications was answered incorrectly. Patient A will then automatically be routed to an alternative description 5 of common complications and an alternative form of the question pertaining to common complications will be presented.

This interactive process may continue for sections on the alternative choices to an abdominal hysterectomy, post-operative care, pre-operative preparation, etc.

- 10 While the patient may be allowed to skip around between sections, certification of informed consent will not be granted until Patient A masters (establishes successful achievement of) each objective. Upon mastery of all objectives, the system will print an informed consent form, listing the key aspects of the interaction, complete with Patient A's name and a signature line, the date and time 15 of consent, and such information. This may be kept for hospital/doctor records, while the complete digital record of the interaction is stored on an internal computer file. Periodically (e.g., monthly) the digital records of all patient interactions will be retrieved from the computer's file and archived for some period. Only after completion of this procedure, in its entirety, including signing of the 20 form, will Patient A be considered to have given her "informed consent" to the abdominal hysterectomy.

The preceding discussion and the claims which follow describe the preferred embodiments of the present invention. Particularly with respect to the claims, it 25 should be understood that changes may be made without departing from its essence. In this regard, it is intended that such changes would still fall within the scope of the present invention. It simply is not practical to describe and claim all possible revisions to the present invention which may be accomplished. To the extent such revisions utilize the essence of the present invention, each would 30 naturally fall within the breadth of protection encompassed by this patent. This is particularly true for the present invention since its basic concepts and understandings are fundamental in nature and can be broadly applied.

VI. CLAIMS

1. A method of establishing certifiable patient informed consent for a medical procedure, said method comprising the steps of:
 - a. evaluating actual legal and medical requirements for establishing informed consent; then
 - b. estimating legal and medical standards for establishing informed consent; then
 - c. defining a set of measurable patient behaviors which can be approximately coincided with said estimated legal and medical standards; then
 - d. interacting with said patient in a standardized fashion to produce measurable patient behaviors; while
 - e. measuring said patient behaviors; then
 - f. approximating satisfaction of said legal and medical requirements.
2. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 1 wherein said step of defining comprises the step of:
 - a. translating said legal and medical standards to measurable behaviors; then
 - b. evaluating the validity of the correlation between said standards and said behaviors.
3. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 2 wherein said step of defining further comprises the step of continuously refining said step of measuring to achieve better approximation between said standards and said measurable behaviors.
4. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 1 or 2 and further comprising the step of

training said patient on desired aspects of said medical procedure.

5. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 1 wherein said step of interacting comprises the steps of:
 - a. periodically testing said patient on aspects to elicit a measurable behavior; then
 - b. evaluating said patient's behavior in response to said step of testing.
- 10 6. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 1 wherein said step of approximating satisfaction comprises the step of achieving defined measurable patient behaviors which approximately coincide with said legal and medical standards.
- 15 7. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 6 wherein said step of approximating satisfaction further comprises the step of statistically establishing a probability of satisfaction.
- 20 8. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 7 wherein said step of statistically establishing comprises the steps of:
 - a. repetitively testing said patient to elicit responses; then
 - 25 b. evaluating said responses.
9. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 4 wherein said step of approximating satisfaction comprises the steps of:
 - 30 a. selecting a minimum criterion that said measurable patient behaviors exhibited coincide with said legal and medical standards; then
 - b. continuing said step of testing until at least said minimum criterion is achieved.

10. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 4 wherein said step of training comprises the step of viewing a learning medium.
- 5 11. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 4 wherein said step of training comprises the step of listening to an audible medium.
- 10 12. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 4 wherein said step of training comprises the step of interacting with a learning medium.
- 15 13. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 4 wherein said step of approximating satisfaction comprises proving mastery of aspects of said medical procedure.
- 20 14. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 13 wherein said step of proving comprises the step of achieving defined measurable patient behaviors which approximately coincides with said legal and medical standards.
- 25 15. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 14 wherein said step of proving further comprises the step of storing said measurable patient behaviors.
16. A method of applying an instructional system development (ISD) model to certify a patient's informed consent to a particular medical procedure, said method comprising the steps of:
 - a. analyzing said medical procedure comprising the steps of:
 - (1) compiling fundamental information on said medical procedure; then
 - (2) selecting information necessary for informed consent; then

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- b. designing a system for training said patient on said selected information; then
 - c. training said patient on said selected information; while
 - d. periodically performing criterion referenced testing on said patient; while
 - e. evaluating said patient's understanding of said selected information; then
 - f. providing certification after patient mastery of all selected information.
- 10
- 17. A method of applying an instructional system development (ISD) model to certify a patient's informed consent as described in claim 16 and further comprising the step of evaluating legal and medical requirements for establishing patient informed consent.
- 15
- 18. A method of applying an instructional system development (ISD) model to certify a patient's informed consent as described in claim 16 wherein said step of analyzing comprises the step of evaluating legal and medical requirements for establishing patient informed consent.
- 20
- 19. A method of applying an instructional system development (ISD) model to certify a patient's informed consent as described in claim 17 or 18 wherein said step of analyzing further comprises the step of estimating legal and medical standards for establishing patient informed consent.
- 25
- 20. A method of applying an instructional system development (ISD) model to certify a patient's informed consent as described in claim 16 wherein said step of training comprises the step of providing a medium to said patient, wherein said medium contains said selected information.
- 30
- 21. A method of applying an instructional system development (ISD) model to certify a patient's informed consent as described in claim 20 wherein said medium is interactive.

22. A method of applying an instructional system development (ISD) model to certify a patient's informed consent as described in claim 16 wherein said step of training comprises the step of removing variance due to individual human character.

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23. A method of applying an instructional system development (ISD) model to certify a patient's informed consent as described in claim 22 wherein said step of training further comprises the step of interacting with said patient.

10 24. A method of applying an instructional system development (ISD) model to certify a patient's informed consent as described in claim 19 wherein said step of periodically performing comprises the steps of:

- posing a set of applicable considerations to said patient, wherein said considerations relate to said selected information; then
- requiring said patient to respond to said considerations.

15 25. A method of applying an instructional system development (ISD) model to certify a patient's informed consent as described in claim 24 wherein said step of providing certification comprises the step of approximating satisfaction.

20 26. A method of applying an instructional system development (ISD) model to certify a patient's informed consent as described in claim 25 wherein said step of approximating satisfaction comprises the step of statistically establishing a probability of satisfaction.

25 27. A method of applying an instructional system development (ISD) model to certify a patient's informed consent as described in claim 26 wherein said step of statistically establishing comprises the steps of:

- repetitively testing said patient to elicit behaviors; then
- classifying said behaviors.

28. A method of applying an instructional system development (ISD) model to certify a patient's informed consent as described in claim 27 wherein said step of classifying comprises the steps of:
 - a. correlating said behaviors to said legal and medical standards; then
 - b. establishing a statistical probability of said correlation; then
 - c. accepting only those established probabilities above a preset minimum.
29. A method of applying an instructional system development (ISD) model to certify a patient's informed consent as described in claim 28 and further comprising the step of re-training said patient on those established probabilities below said preset minimum.
30. A method of applying an instructional system development (ISD) model to certify a patient's informed consent as described in claim 19 wherein said step of evaluating comprises the steps of:
 - a. predetermining an acceptable statistical probability for indicating a correlation between said patient response and said legal and medical standards; then
 - b. periodically computing an actual statistical probability of said correlation; then
 - c. comparing said actual probability to said acceptable probability; then
 - d. continuing said steps of training and performing until said actual probability is at least equal to said acceptable probability.
31. A method of applying an instructional system development (ISD) model to certify a patient's informed consent as described in claim 16 and further comprising the step of proving mastery of said selected information.
32. A method of applying an instructional system development (ISD) model to certify a patient's informed consent as described in claim 31 wherein said step of proving comprises the step of recording said patient's behavioral responses.

33. A method of establishing certifiable patient informed consent for a medical procedure, said method comprising the steps of:
- a. analyzing said medical procedure comprising the steps of:
 - (1) compiling fundamental information on said medical procedure; 5 then
 - (2) selecting information necessary for establishing informed consent; then
 - b. training said patient on said selected information; then
 - c. certifying said patient's understanding of said selected information.
- 10
34. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 33 wherein said step of training comprises the steps of:
- a. presenting said selected information of said medical procedure to said patient; then
 - b. periodically evaluating the patient's understanding of each selected information; and
 - c. automatically determining suboptimal patient understanding of any selected information.
- 15
- 20
35. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 34 wherein said step of certifying comprises the steps of:
- a. re-training said patient in said selected information of suboptimal understanding;
 - b. ensuring mastery in understanding by said patient of each selected information of said medical procedure.
- 25
- 30
36. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 33 wherein said step of training comprises the steps of:
- a. providing information relating to said selected information on a medium; while

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- b. interactively disseminating said information to said patient in a controlled fashion.
- 5 37. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 34 wherein said step of periodically evaluating comprises the steps of:
- a. measuring said patient's response to posed conditions; then
 - b. correlating said responses to said training standards.
- 10 38. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 34 wherein said steps of training and evaluating are interactive.
- 15 39. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 34 wherein said step of periodically evaluating comprises the steps of:
- a. posing a plurality of questions related to said selected information; then
 - b. allowing said patient to respond to said questions.
- 20 40. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 34 wherein said step of evaluating comprises the step of interacting with said patient.
- 25 41. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 40 wherein said step of interacting comprises the steps of:
- a. repetitively querying said patient; then
 - b. permitting patient responses to said queries.
- 30 42. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 34 wherein said step of training comprises the step of interacting with said patient.

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43. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 42 wherein said step of interacting comprises the steps of:

- 5 a. repetitively querying patient; then
- b. permitting patient responses to said queries.

44. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 41 or 43 wherein said step of certifying comprises the step of recording said step of interacting.

10

45. A method of establishing certifiable patient informed consent for a medical procedure as described in claim 36 wherein said medium is selected from the group consisting of interactive video, a book, a record, and a tape.

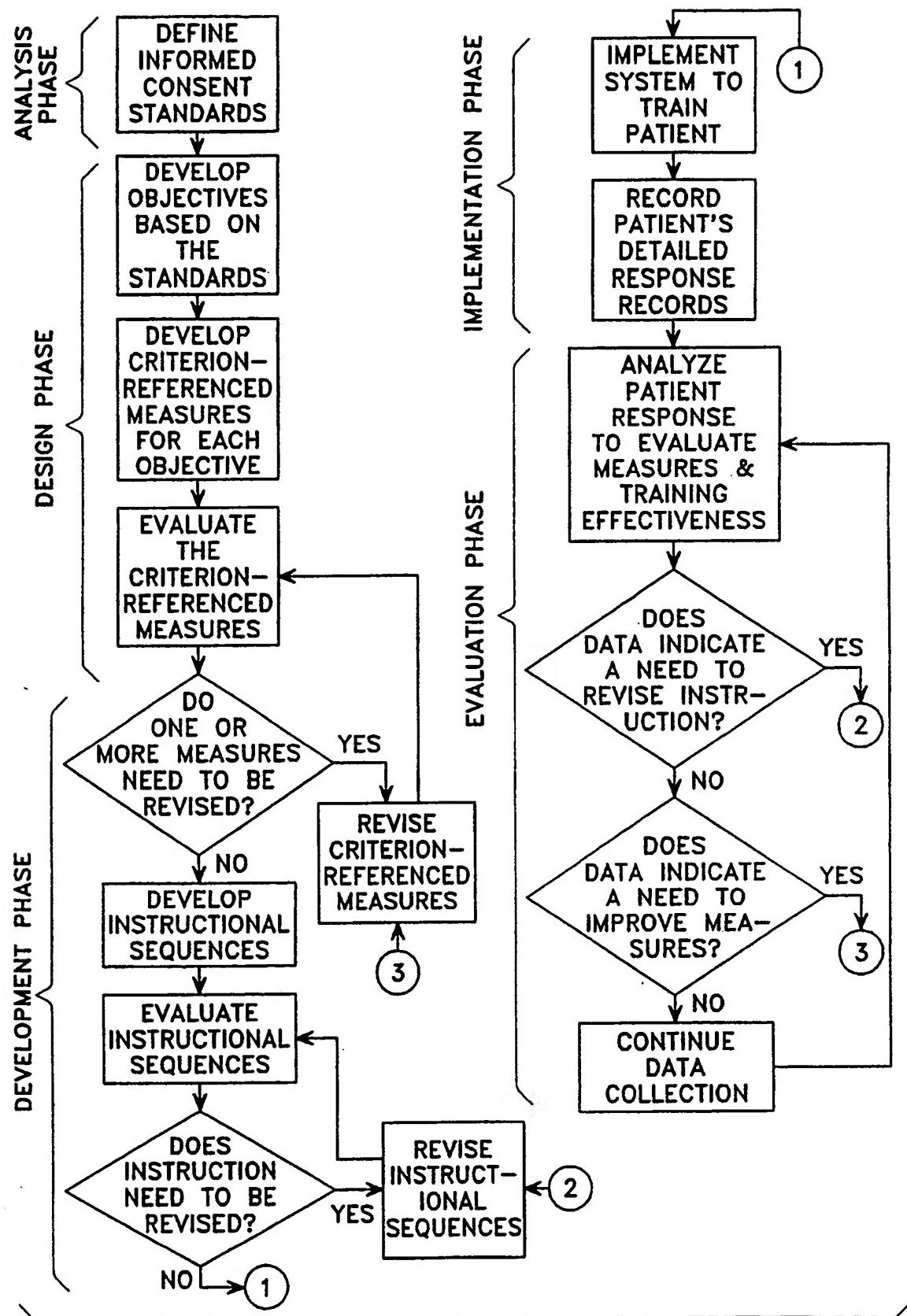


Fig. 1

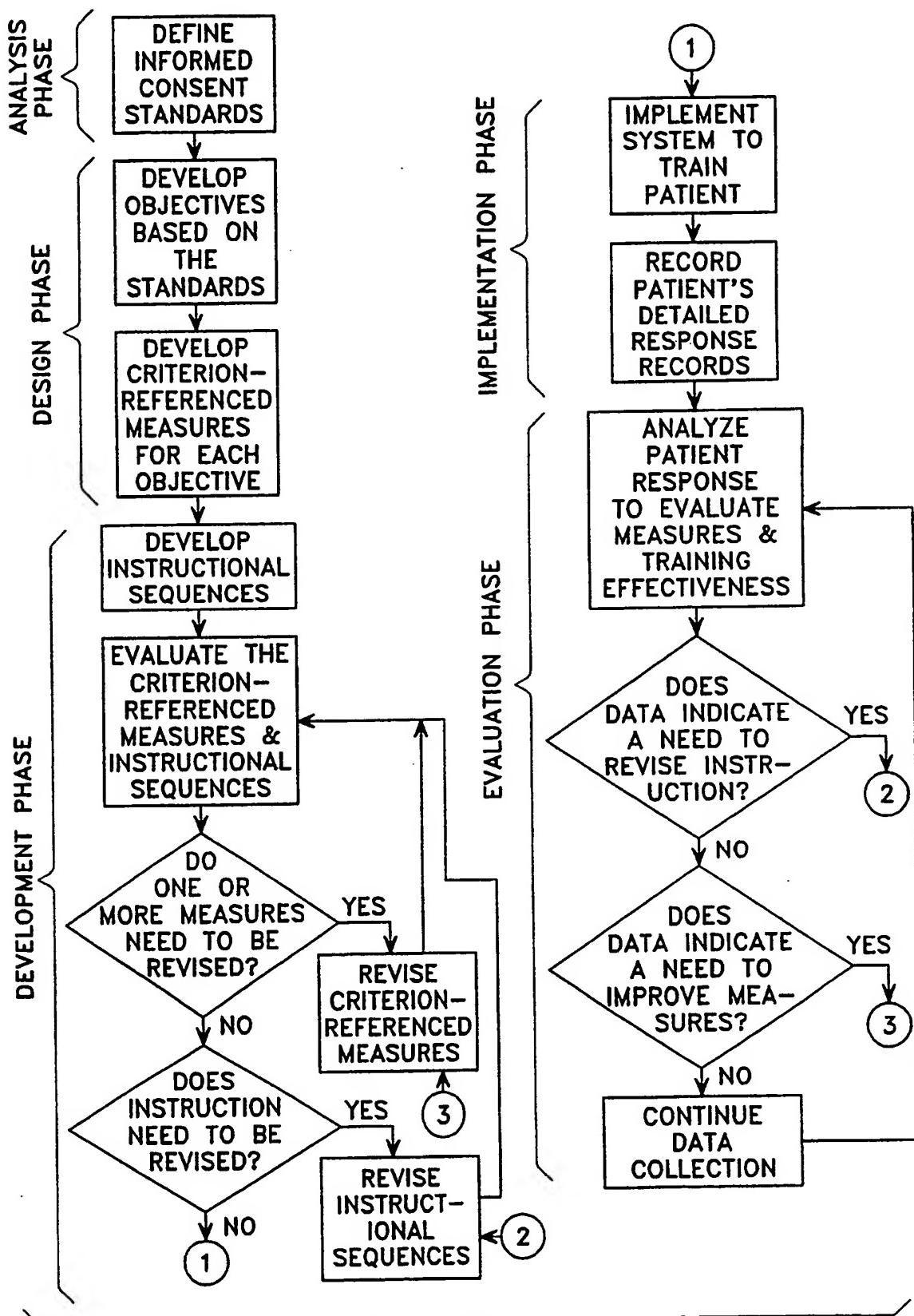


Fig. 2

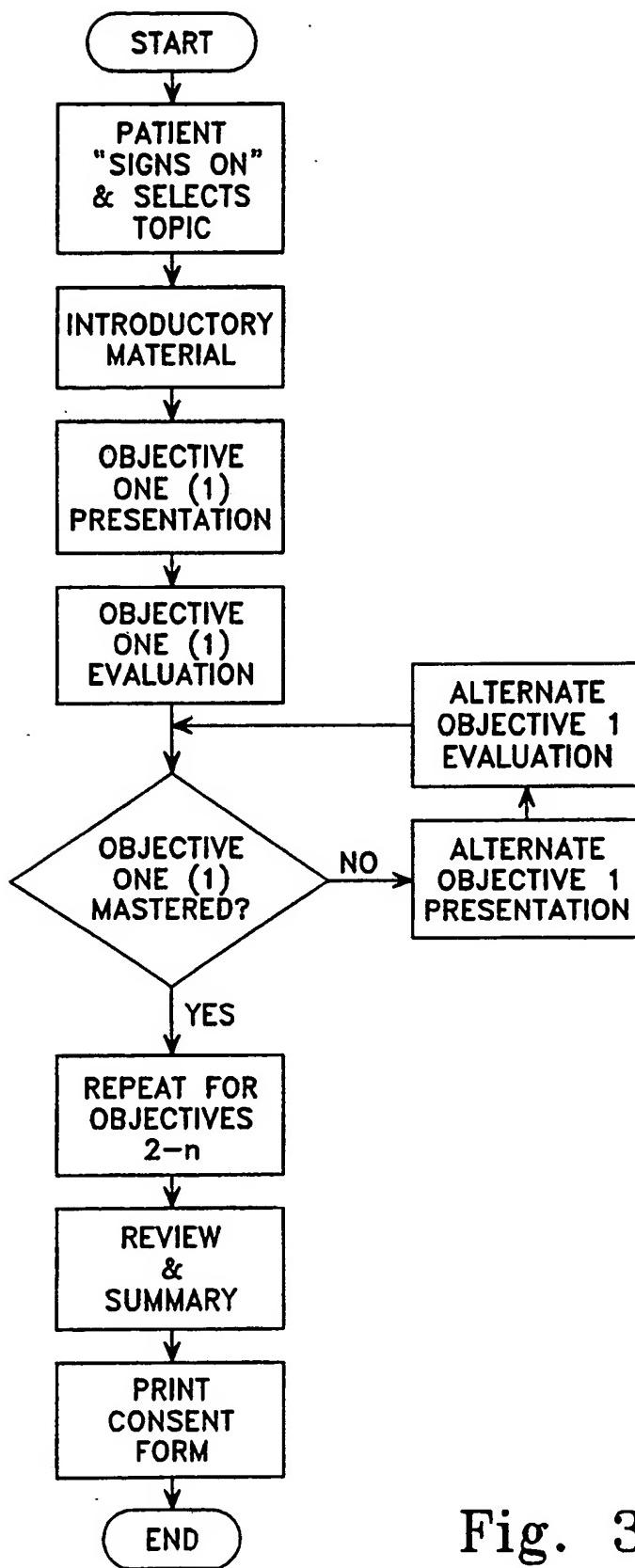


Fig. 3

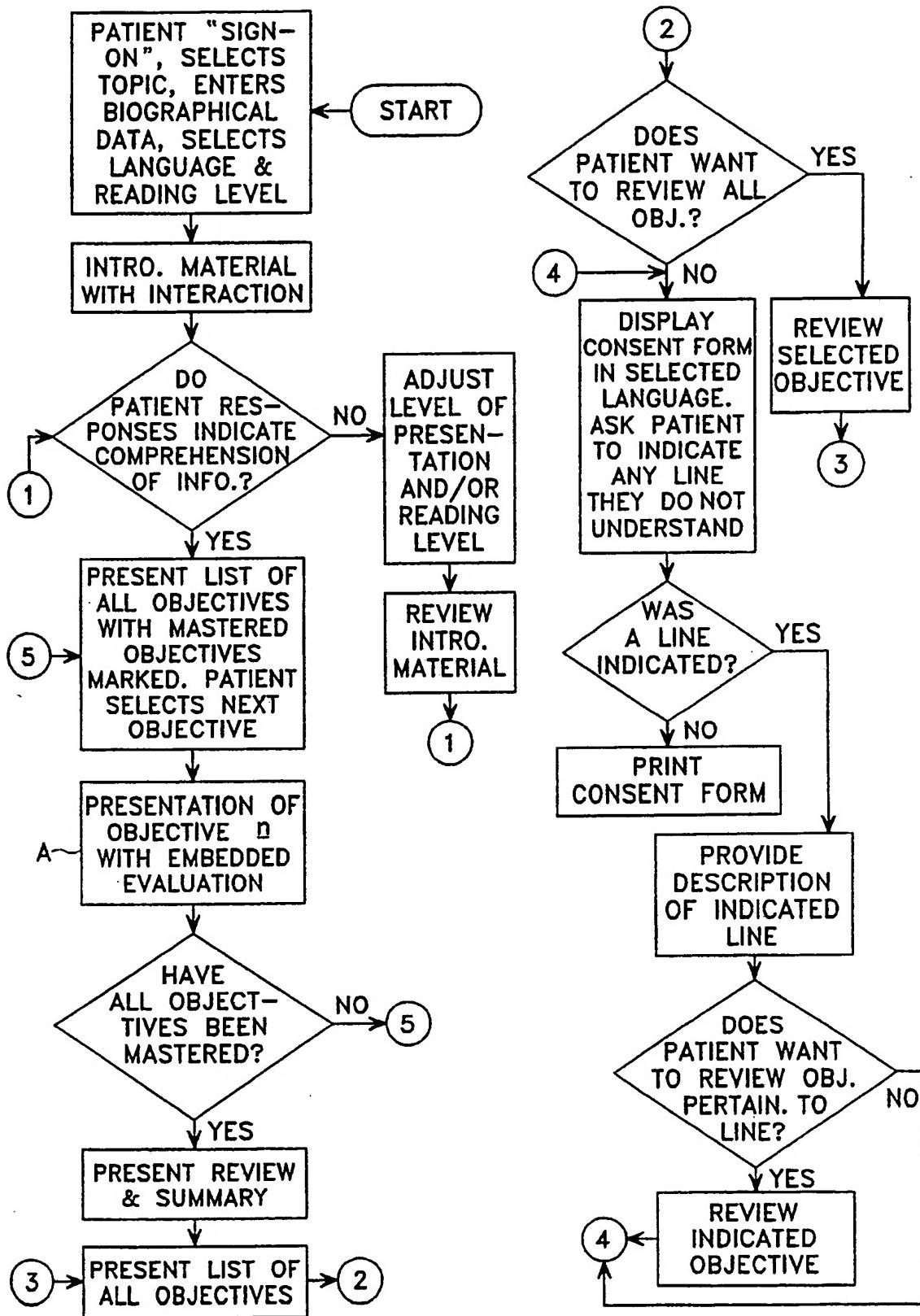


Fig. 4
SUBSTITUTE SHEET

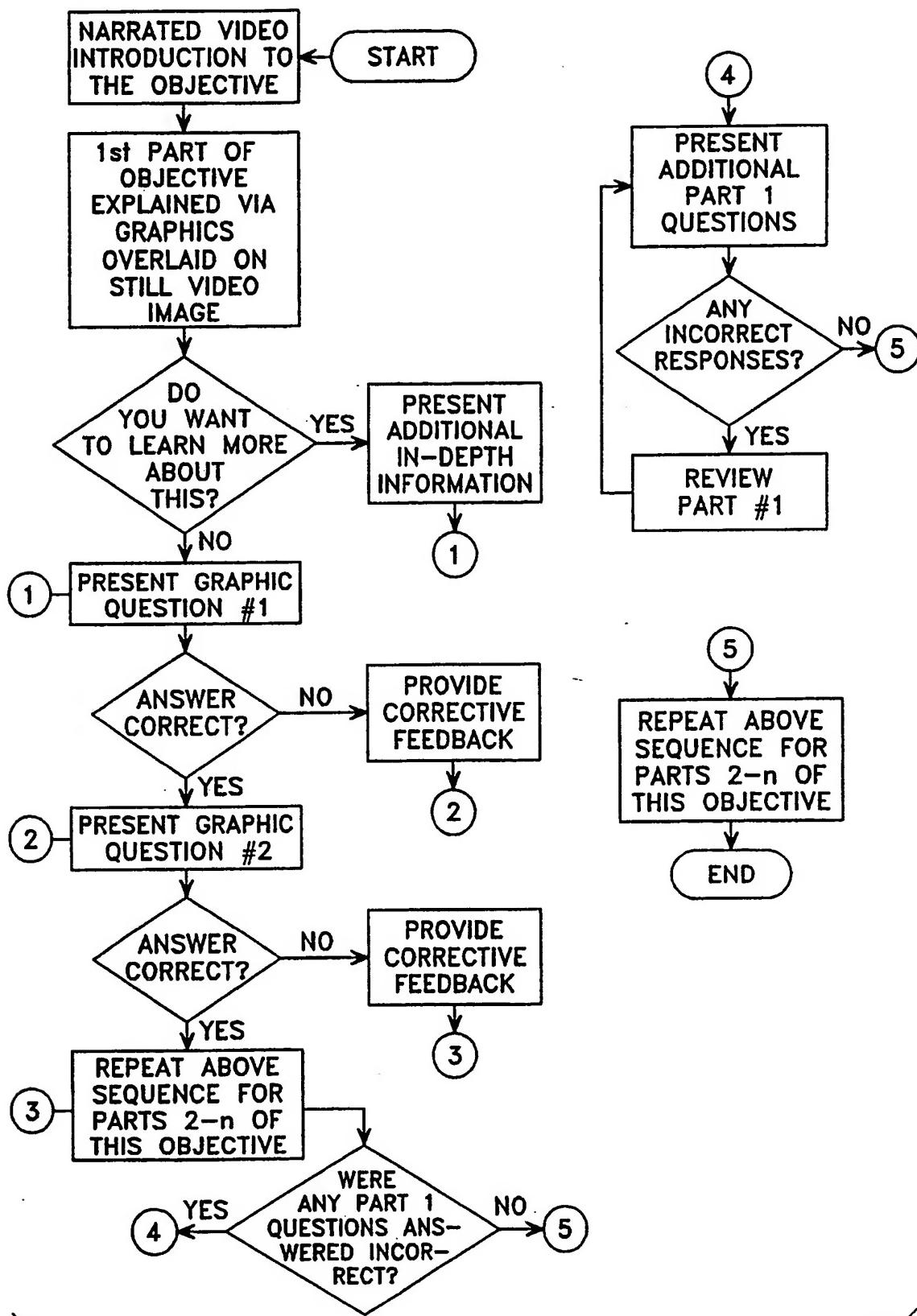


Fig. 5